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European Commission
DG Enterprise & Industry
Pharmaceuticals Unit F2
45 Avenue d'Auderghem
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15 October 2008

Dear Colleagues,

European Commission draft detailed guideline on good clinical practice specific to advanced therapy medicinal products

The BioIndustry Association (BIA) welcomes the opportunity to comment on the European Commission's draft detailed guideline on the GCP requirements for advanced therapy investigational medicinal products.

The BIA is the trade association for innovative bioscience companies in the UK. We represent over 300 members, the majority of which are involved in realising the human health benefits that bioscience promises.

Our comments below represent the feedback from member companies regarding the draft guideline.

General comments

The BIA welcomes the GCP guidance that is specific to advanced therapy medicinal products (ATMPs). In general the draft guideline is comprehensive and well written. It will be useful to companies and other stakeholders involved in the development of ATMPs, providing them with the regulators' expectations of the data requirements.

Specific comments on the text

Section 2.2 Overarching GCP principles

Paragraph 1:
The system should contain sufficient detail to allow linking of each individual product to the individual subject who received the product and back to the donor…

Proposed change: The system should contain sufficient detail to allow linking of each individual product **batch** to the individual subject who received the product and back to the donor...

Comment and rationale: Standard accountability procedures usually do allow traceability to the level of an individual product unit. Where finished products are generated as part of a batch, traceability to batch level is sufficient, since the entire batch must be treated the same. Reconciliation of all units from the batch would be covered by accountability procedures. Traceability to a unit level in these circumstances could be unnecessarily burdensome.

Paragraph 2:
Subjects should be followed-up during and after the completion of the clinical trial…

Proposed change: Subjects should be followed-up during and, **if necessary** after completion of the clinical trial…

Comment and rationale: By adding "if necessary", this clarifies that the need for long term follow-up and, in particular, follow-up after the end of the trial is not always necessary or appropriate. This should be determined on a case-by-case basis using a risk-based approach consistent with section 2.4.2.

Paragraph 3:
The donation, procurement and testing of human cells and tissues used for the manufacturing of an ATIMP should be carried out in accordance with the human cells/tissues and blood Directives...

Proposed change: The donation, procurement and testing of human cells and tissues used for the manufacturing of an ATIMP should be carried out in accordance with the human cells/tissues and**/or** blood Directives....

Comment and rationale: The proposed change clarifies that the appropriate directive would apply depending on the tissue and cells used.

Section 2.4 Safety reporting and long term follow-up

Section 2.4.2 Long term follow-up
We strongly agree with the risk-based approach outlined in this section and stress the importance of this approach as we are dealing with an array of products displaying a range of product characteristics and risks, i.e. topical cell-based products vs. gene therapy products.

Section 2.9 Investigator Brochure
It should be made clear that not all the points listed for consideration should be included in the Investigator Brochure.

Section 2.10 Essential documents

Subsection 2.10.2 During the clinical conduct of the trial - File of the sponsor:
As per comment in section 2.2 above, the link from the ATIMP to the trial site and patient code should be related to the product batch rather than the individual product unit.

Thank you for considering our comments. We would, of course, be pleased to discuss any of them and we look forward to continuing to work with the Commission during the implementation stages of the Advanced Therapies Regulation.

Yours sincerely,

Dr Christiane Abouzeid
BIA Regulatory Affairs Manager